



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/319,521	08/04/99	PITTENGER	VB 640100-326

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EXAMINER
TUNG, M

ART UNIT	PAPER NUMBER
1644	45

DATE MAILED: 09/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/319,521

Applicant(s)
Pittinger, et al.

Examiner
Mary B. Tung

Group Art Unit
1644



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-41 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-41 are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Election/Restriction

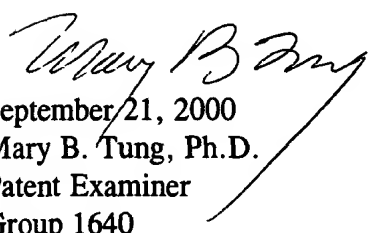
Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

1. Restriction is required under 35 U.S.C. 121 and 372.
2. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. Itay, et al. (US Patent No. 5,053,050 teach a composition comprising mesenchymal stem cells in a three dimensional format and also comprising at least one agent cell growth agent (see the abstract, col. 2, lines 50-54 and col. 3, lines 8-39). The growth agents listed in col. 3, lines 20-22 are interpreted as chondroinductive, as recited in claim 1, since the resulting cells display a chondrocyte phenotype (see col. 3, lines 32-34). Therefore, the '050 patent anticipates the invention recited in claim 1.
3. In accordance with 37 C.F.R. 1.499, Applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.
4. Group I, claims 1-13, 36, and 39, drawn to a composition comprising mesenchymal stem cells, classified in class 435, subclass 372.
5. Group II, claims 14-35, 37, 38, 40 and 41, drawn to a process of producing chondrocytes, classified in class 435, subclasses 377.
6. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:
7. Because a search of any or these three distinct inventions of the patent and non-patent literature would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner.

8. This application contains claims directed to more than one embodiment of the generic invention. These embodiments are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.
9. The Applicant is further required under 35 U.S.C. 121:
10. To elect a **specific chondroinductive agent**: a glucocorticoid, a member of the TGF β superfamily, dexamethasone, or BMP-4, as recited in claims 6-9, 19, 20, 30 and 31.
11. Applicant is required, in response to this action, to elect a specific embodiment to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected embodiment, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.
12. Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional embodiments which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected embodiment. MPEP § 809.02(a).
13. The following claim(s) are generic: claims 1-5 and 14-18.
14. The embodiments listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the embodiments lack the same or corresponding special technical features for the following reasons:
15. A glucocorticoid, a member of the TGF β superfamily, dexamethasone, or BMP-4, differ with respect to their structures, physicochemical properties and uses and are therefore patentably distinct.
16. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
17. Should Applicants traverse on the ground that the members of the species are not patentable distinct, Applicant should submit evidence or identify such evidence now of record showing the members to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

Conclusion

18. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.
19. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The Examiner can normally be reached Tuesday through Friday from 8:30 am to 6:00 pm. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.


September 21, 2000
Mary B. Tung, Ph.D.
Patent Examiner
Group 1640